

**CLINICAL EVIDENCE**



**OPTIMISING & MEASURING  
OUTCOMES IN PRESSURE ULCER  
PREVENTION AND MANAGEMENT**

CLINICAL EVIDENCE  
ISSUE 6

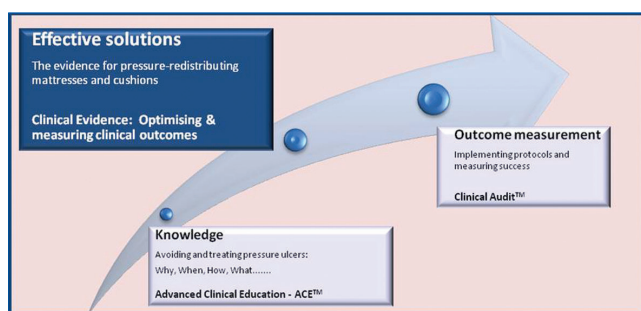
...with people in mind

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In 2006 the Huntleigh Group became part of a leading global supplier of healthcare equipment, Getinge Industrie AB.

As a result of the integration, we are very pleased



to have the opportunity to present evidence arising from two of the most extensively researched design concepts in Active (Alternating) Pressure-Redistributing Mattresses (APRM) and cushions; plus information supporting the use of non-alternating mattresses.

Our formula for optimising outcomes has a foundation in our comprehensive Advanced Clinical Education (ACE™) Programme, which recognises the importance of combining pressure ulcer knowledge with therapeutic

support surfaces and skilled nursing care, while our extensive clinical Assessment Service™ delivers the robust management data required by modern healthcare systems.

**Our 30+ years experience with product and service solutions has achieved, and in many cases exceeded, expectation.**

We invite you to dip into this **Clinical Evidence Booklet** where we feature a range of clinical studies from simple case series through to randomised controlled studies; we also invite you to read our sister publications:

- **The Principles of Alternating Pressure:** the rationale behind the most effective and logical approach to pressure ulcer management.
- **Therapeutic Patient Positioning:** the evidence for rotational and prone nursing in critical care.
- **The Importance of Seating:** recently updated, balancing quality of life and patient choice with risk management in the seated patient.

# Pressure Ulcers: An Introduction

## Pressure Ulcers

Pressure ulcers, **“Localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear.”**<sup>1</sup> are generally classified by severity into 1 of 4 discrete categories (figure 1).

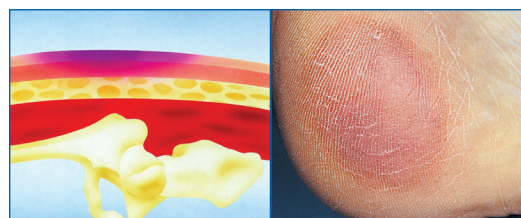
The 2009 International Pressure Ulcer Guidelines<sup>1</sup> highlight that practitioners may also use 2 additional categories for those wounds which are considered ‘unstageable’ due to the presence of slough or eschar (figure 2) or those wounds which are suspected to represent ‘deep tissue injury’ beneath intact skin (figure 3)<sup>2</sup>.



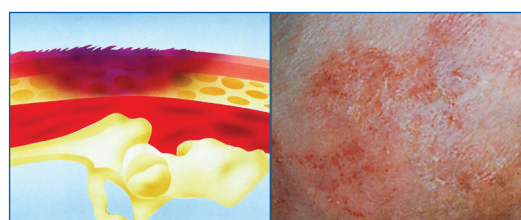
Figure 2: Unstageable/unclassified - depth unknown



Figure 3: Deep Tissue Injury



Category 1



Category 2



Category 3



Category 4

Figure 1: EPUAP/NPUAP 2009<sup>1</sup>

All categories of pressure ulcer referred to in this document are from The International Guidelines unless otherwise stated.

## The Avoidable Epidemic

Pressure ulcers are common and have been reported in up to 1 in 5 patients in both Europe<sup>3</sup> and the US<sup>4</sup> (figure 4)<sup>3</sup> and yet, with effective preventative care they are considered largely avoidable<sup>5</sup>.

Cost is high with the UK spending up to 4% of the healthcare budget on pressure ulcer management<sup>6</sup>; this equates in present day costs to more than £19 million per year in an average 500 bed UK hospital<sup>7</sup> while the USA is spending in the region of \$3.6 billion per annum<sup>8</sup>.

Given the economic and humanitarian burden, pressure ulcers are increasingly becoming the focus of quality and safety initiatives, with some healthcare systems imposing severe punitive measures on healthcare providers if ulcers occur within a supervised facility<sup>9</sup>.

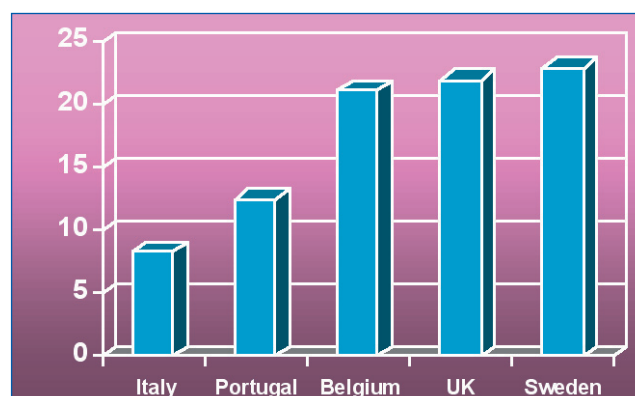


Figure 4: European Prevalence Data by Country

# Pressure Ulcers: An Introduction

## Pathophysiology

The body has evolved to tolerate short periods of high pressure or longer periods of low pressure; this is characteristic of every day life. However when independent mobility and tissue tolerance is affected by illness or infirmity the risk of pressure ulceration increases. Prolonged compression and/or distortion of subcutaneous tissue can reduce the supply of essential oxygen and nutrients to the tissue resulting in a build up of toxic metabolites.

Pressure on the skin as low as 6 mmHg can occlude capillary blood flow<sup>10,11</sup> and with a wide individual variation (figure 5), it is impossible to say what is a 'safe' level for each individual.

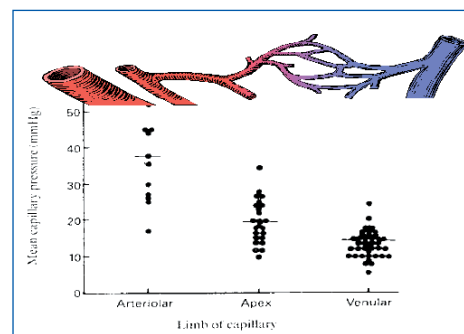


Figure 5

## Normal Physiological Response To Pressure

Healthy individuals make subconscious movement every few minutes in order to avoid prolonged pressure, even during sleep<sup>12,13</sup>. This movement off-loads the tissue and reperfusion occurs through a process of 'reactive hyperaemia' which is a 'flush' of blood to the tissue. This **normal physiological response** replenishes the tissue with oxygen and nutrients and removes toxic waste: this may be visible on the skin surface as a reddened area (erythema) which blanches (whitens) under light finger pressure.

*Note: This phenomenon should not be confused with redness that persists and does not blanch (category 1 pressure ulcer) or with the reperfusion that occurs after prolonged ischaemia and is associated with reperfusion injury.*

## Preventative And Therapeutic Strategies

Active (alternating) pressure-redistributing support surfaces mimic spontaneous body movement by repeatedly and automatically off-loading the tissue by means of inflating and deflating sections of the mattress or cushion. The effect can be measured in the laboratory using Interface Pressure (IP) and Doppler perfusion studies, and the rationale behind the development of these devices is explored in much more detail in **The Principles of Alternating Pressure** brochure, available from ArjoHuntleigh.

Active (alternating) pressure unlike other modalities, was designed purely for pressure ulcer management and as such, is supported by the widest range of clinical evidence from extensive all-comer clinical outcome studies to specialist care such as intensive care, burns, spinal injury and reconstructive surgery.

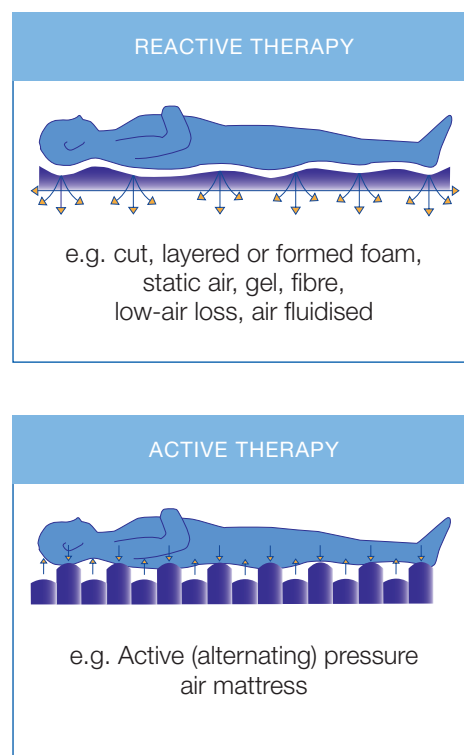


Figure 6: Therapy Modes



## Active (Alternating Pressure)

Active (alternating) Pressure Redistributing Mattresses (APRM) deliver therapy by means of cyclical pressure redistribution; this serves to periodically off-load the tissue and restore blood flow.

The goal of an APRM is to deliver **TRUE ALTERNATING** pressure by producing an off-loading profile which mimics normal spontaneous movement:

- 6–8 times every hour
- Pressure as low as possible
- Low pressure held for as long as possible to enable reperfusion of the tissue

Despite being of similar appearance each mattress is designed to perform in different ways as determined by **cycle frequency, duration** and degree of off-loading (**amplitude**). A change in just one of these parameters can produce a measurable effect on **tissue perfusion** and it follows that clinical outcomes will be influenced by the performance characteristics.

The clinical evidence which follows can only be considered relevant to the product, or product family described in the reports; it may be highly misleading to assume similar outcomes will be achieved for different APRM devices.

## Evidence from Randomised Controlled Trials (RCTs)

*RCTs, the ‘gold standard’ in research are complex to undertake and so are rare in the field of wound care. Such studies are designed to evaluate the effectiveness of one product, or one modality compared to another.*

A pilot randomised controlled trial comparing reactive air and active alternating pressure mattresses in the prevention and treatment of pressure ulcers among medical ICU patients (*Malbrain et al 2010*)

- Nimbus® 3 mattress vs. ROHO® mattress (ROHO Inc.).
- Compared pressure ulcer outcomes in **16 randomly assigned subjects**.
- In the *Nimbus* 3 group 62.5% of subjects had existing wounds of which 82% improved; no ulcers improved in the ROHO group.
- The *Nimbus* 3 mattress was shown to be the more effective device<sup>14</sup>.

Comparing the effectiveness of a specialized alternating pressure air mattress replacement system and an air-fluidized integrated bed in the management of post-operative flap patients. A pilot RCT (*Finnegan 2008*)

- *Nimbus* 3 Professional APRM (ArjoHuntleigh) vs. Clinitron® Rite Hite® Air Fluidized Bed (Hill-Rom Inc.).
- Compared surgical site integrity, pressure ulcer incidence and cost of bed/mattress provision in **40 randomly assigned subjects** undergoing major reconstructive surgery.
- Excellent clinical outcomes were observed in both groups but the cost of air fluidized therapy was double that for *Nimbus* 3 Professional mattress.
- Subjects expressed a clear preference for *Nimbus* 3 Professional mattress in terms of comfort, independent mobility, temperature and overall satisfaction<sup>15</sup>.

## Evidence from Randomised Controlled Trials (RCTs) - continued

### Pressure relieving support surfaces (PRESSURE) trial: cost effectiveness analysis (Iglesias et al 2006)

- **1971 subjects** within 11 acute care hospitals (UK) were randomly assigned to a Mattress Replacement (MR) or a mattress overlay.
- Alternating pressure mattresses were 80% more likely to be cost saving compared to mattress overlays, mainly due to reduced length of stay in hospital and a delay in time to ulceration.
- MR's were more acceptable to patients than overlays<sup>16</sup>.

*Note: this study was independently funded and included a range of different alternating support surfaces including Nimbus 3 mattress.*

### Do different mattresses affect the quality of cardiopulmonary resuscitation? (Perkins et al 2003)

- A randomised controlled cross-over study comparing Cardio Pulmonary Resuscitation (CPR) and ventilation efficiency on four different surfaces: floor; foam mattress; inflated and deflated *Nimbus 3* mattress.
- There were no efficiency differences noted between the 3 mattresses and the deflation process did not affect the outcome.
- The study does not support routine deflation of APRMs for CPR: bed height is the critical factor<sup>17</sup>.

### Comparing the cost: A study of the AlphaXcell® alternating pressure mattress overlay system compared with the Tempur® foam mattress overlay in combination with patient repositioning (Folens 2001)

- 4-hourly repositioning on a Tempur foam mattress (Tempur UK Ltd) was compared to an *AlphaXcell* overlay (ArjoHuntleigh) with no routine repositioning in **504 subjects**.
- There was no statistical difference in the development of pressure ulcers between the 2 groups.
- Repositioning activity is a high resource cost; the *AlphaXcell* overlay is a more cost-effective option<sup>18</sup>.

### Randomised controlled trial of two pressure-relieving systems (Russell et al 2000)

- *Nimbus 3* mattress vs. Cairwave® Therapy System (Pegasus UK).
- Compared healing rates in **141 randomly assigned elderly care subjects**.
- Equally effective for sacral ulcers with improved outcomes for heel ulcers in the *Nimbus 3* mattress group.
- Both systems equally comfortable and a high level of subject acceptability<sup>19</sup>.

### A clinical evaluation of the Nimbus 3 alternating pressure mattress replacement (Evans et al 2000)

- **32 subjects** were randomly assigned a *Nimbus 3* APRM or an alternating overlay system.
- The *Nimbus 3* mattress was significantly more comfortable with faster healing rates<sup>20</sup>.

### A clinical evaluation of an alternating pressure mattress replacement system in hospital and residential care settings (Land et al 2000)

- Compared healing rates for a *Nimbus 3* mattress vs. alternating overlay in subjects with category 3 or 4 pressure ulcers.
- The *Nimbus 3* mattress was more comfortable and more effective compared to the overlay group; mean area reduction for ulcers was 5% per day<sup>21</sup>.

### Evaluating the Pegasus Trinova®: a data hierarchy approach (Taylor 1999)

- **44 subjects** were recruited from general medicine/ surgery and randomly assigned either the *Trinova* MR or an alternative APRM.
- No subject in the *Trinova* mattress group developed tissue damage.
- Patient and staff questionnaires highlighted the *Trinova* mattress was well accepted and patients found it comfortable<sup>22</sup>.

## Evidence from Prospective Outcome Studies

Outcome studies are illustrative descriptions of one or more patients often presenting with complex, challenging or rarely encountered conditions. Such rich data, particularly when combined with other data sources, are an invaluable source of information for clinicians.

**All** the support surfaces detailed below have one thing in common: they have been **specifically designed** to provide **TRUE ACTIVE (ALTERNATING) PRESSURE**. Each system has been developed to cyclically hold pressure at the skin:surface interface as **LOW AS POSSIBLE FOR AS LONG AS POSSIBLE**.

## Multi-centre or large cohort studies

The value of systematic evaluation in determining the effectiveness and practical utility of a pressure-redistributing support surface (Ward 2010)

- Sixty hospitalised patients at risk of or with existing pressure ulcers were prospectively studied whilst being nursed on the Alpha Response™ System.
- Only one patient developed non-blanching erythema.
- Seventy percent of patients with existing pressure damage (included 4 patients with full thickness pressure ulceration) healed or improved.
- Utility of the system was well received from hospital staff<sup>23</sup>.

The effectiveness of the AUTO logic® 200 system in the prevention and healing of pressure ulcers (Winjands et al 2006)

- **100 subjects** Intensive Treatment Unit (ITU) were recruited (Belgium): 80 had intact skin on recruitment; 20 had existing ulcers.
- Healing: 10 out of 20 subjects improved or healed completely, n = 9 remained stable.
- Prevention: 91 subjects avoided new or further tissue damage.
- No subject developed signs of tissue damage beyond category 1<sup>24</sup>.

Evidence-based practice and support surfaces: are we throwing the baby out with the bath water? (Clark et al 2005)

- A two-centre prospective study across 8 medical specialities following the outcome of **219 subjects** (UK), 73 of whom had existing tissue damage.
  - Nimbus logic® 200 system (ArjoHuntleigh) 49 subjects – 96% remained ulcer free

- AUTO logic 200 system (ArjoHuntleigh) 102 subjects – 99% remained ulcer free
- AUTO logic 110 system 68 subjects – 96% remained ulcer free
- All ulcers present on admission either healed or were improving at the point of discharge<sup>25</sup>.

Low weight patients (ArjoHuntleigh 2004)

- **38 subjects** (22–40 kgs) were nursed upon Nimbus, Autoexcel® (ArjoHuntleigh) or AlphaXcell systems.
- 19 subjects who had ulcers on admission improved and did not incur new damage.
- 19 subjects with intact skin on admission remained ulcer free.
- 97% of subjects rated the systems as comfortable or very comfortable<sup>26</sup>.



Figure 7: Alpha Response Active Therapy System

## Evidence from Prospective Outcome Studies - continued

A retrospective study to determine the incidence of pressure ulcers in burn patients using an alternating pressure mattress (*Still et al 2003*)

- **186 subjects** with serious full thickness burn injuries were recruited from a tertiary burn centre (USA).
- Subjects were nursed on the *Cairwave* Therapy System.
- Repositioning schedules were individualised and depended on the subjects overall condition.
- No pressure ulcer developed in this very high risk population<sup>27</sup>.

A prospective clinical outcome study of the effectiveness of a dynamic mattress replacement system in the critically ill patient (*Marin 2002*)

- **23 critical care subjects** from within 3 major hospitals (Spain); were allocated the *Trinova* MR System.
- 70% of patients were ventilated; 87% of patients were immobile and 43% not repositioned.
- Mean length of stay was 11 days; existing pressure ulcers improved.
- 3 patients developed superficial tissue loss associated with incontinence; resolved with skin care<sup>28</sup>.

Defining the rate of healing of pressure ulcers (*Wallenstein et al 2002*)

- **96 subjects** (intensive care) with category 2, 3 and 4 ischial, trochantric or pelvic pressure ulcers were allocated a *Cairwave* Therapy System (USA).
- Statistical analysis was performed to establish the rate of wound healing over 8 weeks and to establish those variables that have an impact on wound healing.
- The initial rate of healing of pressure ulcers was 12% per week.
- The wound size of all pressure ulcers reduced by 50% at week 4<sup>29</sup>.

Models of pressure ulcer care: costs and outcomes (*Clark M 2001*)

- The data from **2507 subjects**, prospectively studied within 4 UK hospitals were used to construct a cost model.
- All pressure ulcer preventative strategies were incorporated; including manual repositioning and a wide range of constant low pressure and alternating pressure support surfaces.
- Alternating therapy is more cost-effective than all other treatments (including surgery) for patients with category 3 or 4 ulcers or those at highest risk<sup>30</sup>.

*Note: this is possibly the largest, commercially sponsored, prospective pressure ulcer study undertaken to date.*

Cost-effective strategy for managing pressure ulcers in critical care: A prospective, non-randomised, cohort study (*Phillips 2000*)

- A multi-centred non-randomised, prospective clinical outcome study across 5 facilities within the UK.
- **160 critically ill subjects** were nursed upon the *Cairwave* Therapy System or its predecessor.
- Of 30 subjects who had ulcers on recruitment, 46.7% improved or healed prior to transfer.
- 6 (3.8%) subjects developed new tissue damage (n= 5 superficial); all were associated with non-mattress related factors<sup>31</sup>.

Pressure ulcer management in critical care (*Calver 1999*)

- **47 subjects** were allocated a *Cairwave* Therapy System on recruitment to a two-phase, multi-centre study (UK).
- All were immobile, 43 were ventilated and 19 patients haemodynamically unstable; 12 patients presented with skin damage on admission.
- Progress was reported for 7 of the 12 ulcers encountered, of these; 4 were reported to be healed or healing and 3 remained the same.
- 91.5% of subjects were protected from new or additional ulcers<sup>32</sup>.



## Individual cases or case series from the specialist care sector

*Although traditionally case study evidence is considered weak, a great deal of information can be conveyed that would be lost in a more controlled type of study this is particularly important in the specialist environment.*

### BURNS

#### Evaluation of an alternating pressure support surface for burn treatment (*Mathews 2003*)

- A 50 year old man with 30% full thickness burns following an industrial explosion was hospitalised for 2 months.
- The patient was nursed on a low air loss therapy system and discharged home using a *Nimbus 3* system.
- The patient preferred the *Nimbus 3* system to previous support surfaces, as it was more comfortable and promoted healing<sup>33</sup>.

#### Use of the Nimbus 3 mattress in a patient with severe burns: A case study (*Vrijdag et al 2001*)

- A 28 year old man with 41% burns following a house fire with a full thickness burn injury on his back and severe inhalation injury resulting in Acute Respiratory Distress Syndrome (ARDS) was nursed on the *Nimbus 3* system.
- Nursing and physiotherapy staff preferred the *Nimbus 3* system, as there was increased patient access.
- The patient healed and was discharged after 48 days<sup>34</sup>.

### OBESITY

#### Speciality support surface selection for hospitalized obese patients (*Manriques 2004*)

- A Contoura® 1080 bed frame (ArjoHuntleigh) was used with a *Nimbus 3* alternating MR. It was found to be highly acceptable to both patients and nursing staff.
- Cost was significantly lower than using integrated systems with a \$48,000 saving noted, combined with an increase in the quality of care<sup>35</sup>.

#### AUTO logic system clinical outcome study (*Henn et al 2004*)

- **7 patients**, all weighing in excess of 100 kg were nursed on either the *AUTO logic 110* overlay or *AUTO logic 200* MR.
- 1 patient had existing category 2 pressure damage.
- No patient developed tissue damage and the patient with an existing pressure ulcer healed<sup>36</sup>.

#### Achieving handling excellence for the larger patient with a specialist 'transfer chair' (*Thompson 2004*)

- A patient weighing 242 kg with compromised cardiac output and severe cellulitis was admitted to an acute UK hospital and nursed on a *NIMBUS logic 200* system.
- The transfer chair (TC300®) (ArjoHuntleigh) was evaluated. Staff were able to easily transfer the patient using the chair, causing no tissue damage and without the use of hoists or slings.
- The patient was very enthusiastic about the new products<sup>37</sup>.

## Individual cases or case series from the specialist care sector - continued

### Pressure relief and the critically ill bariatric patient (*Phillips 2001*)

- **19 subjects** weighing more than 100 kgs were admitted to a major tertiary burns unit (USA) and allocated a *Cairwave* Therapy System.
- More than 50% were ventilated and not regularly repositioned.
- No pressure ulcers developed during the study period (1–80 days).
- Using the *Cairwave* Therapy system the study concluded that bariatric, critically ill patients can expect the same outcomes in terms of pressure ulcer prevention as a less heavy patient<sup>38</sup>.

### RECONSTRUCTIVE SURGERY

#### Successful healing and cost effective care for post-operative flap repair of a pressure ulcer (*Schaffer 2002*)

- A 63 year old obese paraplegic man with a deep category 4 pressure ulcer<sup>1</sup> over the ischial tuberosity required muscle flap reconstruction.
- The *Nimbus* 3 system was used in place of an air fluidised system.
- Complete healing occurred, the patient was comfortable and a cost saving of 52% was achieved<sup>39</sup>.

#### Alternating support surface effectiveness with a muscle flap closure of a pressure sore (*Doubleman 2001*)

- A 52 year old obese man within surgical ICU with a complex history of chronic respiratory failure, osteogenesis imperfecta, chronic osteomyelitis and quadriplegia.
- A pressure ulcer had developed over the site of the greater trochanteric screw, requiring excision, osteotomy and muscle flap closure.
- The patient was nursed on a *Nimbus* 3 system with excellent results, the wound healed and the patient found the support surface comfortable<sup>40</sup>.

### SPINAL CORD INJURY

#### Pressure sores in spinal cord injury: Active intervention saves costs (*Dunn & Stander 2008*)

- Introduction of pressure ulcer policy into Spinal Unit including turning teams, staff education and utilisation of *Nimbus* and *Autoexcel* alternating systems.
- Pressure ulcer incidence fell from 16% to zero.
- Significant cost savings made<sup>41</sup>.

#### Back to basics – Simple measures resolve a complex wound: Pressure off-loading and honey (*Ashton et al 2006*)

- A 64 year old female with spinal cord injuries with an infected sacral pressure ulcer, unhealed for 3 months.
- The patient was placed on a *Nimbus* 3 Professional with complete off loading and simple honey dressings.
- The wound made rapid progress towards complete closure<sup>42</sup>.

#### Management of pressure with an alternating pressure relieving support surface (*Doubleman J 2000*)

- A patient with Spinal Cord Injuries (SCI) stabilised with a halo device was placed on a *Nimbus* 3 system.
- The patient sustained no pressure injuries whilst on the *Nimbus* 3 system, despite being unable to reposition independently<sup>43</sup>.

## VASCULAR SURGERY

An evaluation of alternating pressure for patients undergoing vascular surgery: a new mattress replacement system with a low pressure heel section (*Fox et al 2000*)

- Following vascular surgery **30 immobile patients** were nursed on the *Nimbus 3* system.
- No mattress related pressure injuries occurred, with the exception of one patient.
- The system was found to be easy to use and provided good pressure relief particularly on the heels<sup>44</sup>.

## PAEDIATRICS

Caring for a severely disabled child - what a difference a good night's sleep makes! (*Tweed 2009*)

- Case study where *Nimbus* Paediatric System was used in caring for a severely disabled four year old child
- Skin integrity was maintained, comfort levels improved, sleep quality and quantity increased, respiratory function was enhanced
- Parents highly satisfied with *Nimbus* Paediatric System<sup>45</sup>.

Pressure area care in infants and children: *Nimbus* Paediatric system (*Jones et al 2001*)

- 22 critically ill infants and children were nursed upon the *Nimbus* paediatric mattress for between 1 and 7 days.
- Average age was 12.7 months.
- No pressure injuries occurred.
- One infant with an existing wound began to heal<sup>46</sup>.



Figure 8: *Nimbus* Paediatric System

## COMPLETE PRESSURE OFF-LOADING USING WOUND VALVE TECHNOLOGY

The *Nimbus 3*, *Nimbus 4* and *Nimbus Professional* pressure redistributing mattress replacements: Combining Active (alternating) therapy with Wound Valve™ Technology for the prevention of pressure ulcers and the management of complex wounds in high risk patients (*Phillips 2010*)

### Wounds UK (2010). In Press

- Product focus highlighting benefits of active pressure redistribution for patients at risk of pressure ulceration
- Pressure redistributing support surfaces classified into reactive (constant low pressure) and active (periodic removal of pressure from the body).
- Active support surfaces recommended by international guidelines as modality of choice for immobile patients.
- Specific features of some products (*Nimbus 3*, *Nimbus 4* & *Nimbus Professional*) have specialist features enabling complete pressure relief over vulnerable areas<sup>47</sup>.

Using complete pressure off-loading and advanced wound care to treat a complex sacral pressure ulcer (*Ward et al 2010*)

- Category 4 pressure ulcer in an 81 year old acutely ill patient with complex co-morbidities.
- Holistic assessment and care package instigated. Wound debridement and advanced dressing products used.
- Complete and continuous pressure off-loading achieved using wound valve technology as part of the *Nimbus Professional* mattress replacement system.
- Medical condition improved along with significant reduction in size and depth of pressure ulcer<sup>48</sup>.



Figure 9: *Nimbus Professional* Mattress Replacement System

## Evidence from Laboratory Studies

Although the RCT is considered to be the best research design used to provide evidence of efficacy, such studies are notoriously difficult to organise, fund and recruit for<sup>49</sup>. Laboratory data, although not directly indicative of clinical outcome, can provide clinicians with a valuable source of information, particularly when combined with other sources of evidence.

Laboratory tests are generally reported in two ways:

- A simple description of the performance characteristics, Pressure Relief Index (PRI) of a device.  
*Internal test protocol – usually single subject – unpublished data.*
- A formal study comparing the performance characteristics of two or more similar devices  
*Independent test laboratory – multiple subjects – published data.*

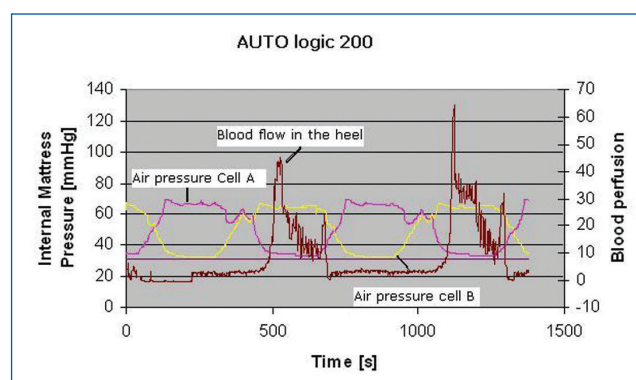


Figure 10

The laboratory study is perhaps the best method of clearly illustrating the **very different performance characteristics** of support surfaces. Differences in **AMPLITUDE**, **CYCLE TIME** and/or **DEGREE OF OFF-LOADING** have been shown to have a measurable affect on tissue perfusion (Figure 10).

### Is dynamic seating a modality worth considering in the prevention of pressure ulcers? (Stockton et al 2008)

- Laboratory study performed to determine if an alternating cushion can perform as well as a static cushion combined with periodic off-loading
- 8 healthy volunteers tested on 3 different cushion types; one alternating (AURA logic®), one foam and one gel
- Subjects sat for 20 minutes on each cushion; for the alternating cushion, no movement took place. For the static cushions, subjects sat for 20 minutes followed by a “lean forward” movement for 20 seconds
- Laser Doppler and interface pressure measurements were undertaken on each ischial tuberosity
- Highest perfusion rates correlated with the AURA logic
- Lowest interface pressures were from the AURA logic during the deflation phase of the cycle
- If there is doubt that the patient will perform frequent off-loading, the use of an alternating cushion should be considered<sup>50</sup>.

### Physiological response of the heel tissue on pressure relief between three alternating pressure air mattresses (Goossens et al 2008)

- 11 adult volunteers were tested.
- AUTO logic 200 system exhibited lower maximum and lower minimum IP and produced a significantly superior PRI (below 30 mmHg) when compared to either the DuoCare Plus™ (Talley Medical) ( $p < 0.002$ ) or Proficare® (KCI Inc) ( $p < 0.0001$ ) systems.
- AUTO logic 200 system produced significantly enhanced perfusion (blood flow) when compared to either DuoCare Plus ( $p < 0.03$ ) or Proficare ( $p < 0.01$ ) systems<sup>51</sup>.



### Alternating pressure redistribution mattresses: appearances can be deceptive (*Rithalia 2007*)

- Compared Duo 2® (Hill Rom Inc) and *Nimbus logic* systems with their predecessors to illustrate how design improvements effect tissue perfusion in normal and diabetic volunteers.
- Only *Nimbus 3* and *Nimbus logic* systems held IP below 30 mmHg.
- Tissue perfusion in 16 diabetics was significantly greater ( $p < 0.001$ ) for *Nimbus 3* system than for Duo system.
- Tissue perfusion in 14 normal subjects was significantly greater ( $p < 0.001$ ) for *Nimbus logic* system than for Duo 2 system<sup>52</sup>.

### Effect of support surface design on skin temperature (*Heath et al 2006*)

- Compared temperature and relative humidity (RH) at the skin-mattress interface between a Breeze® low air loss mattress (ArjoHuntleigh), *AUTO logic 200* mattress and a pressure redistributing foam mattress using 3 volunteers.
- Temperature and RH increases were similar for both low air loss (1.2°C; RH +18%) and alternating therapy (1.6°C; RH +19%) compared to foam (3.3°C; RH +51%).
- Conclusion: the performance of low air loss and *AUTO logic 200* mattresses are similar and control the tissue micro-climate more efficiently than foam<sup>53</sup>.

### Heel blood flow studies using alternating pressure air mattress systems in diabetic patients (*van Schie et al 2004*)

- Comparing the heel blood flow in **14 diabetic subjects**, with and without neuropathy, on the *Nimbus 3* system and the Duo system.
- Blood flow (measured by Doppler flowmetry) was higher for subjects on the *Nimbus 3* system, highlighting the superiority of cycles that alternate high pressure with low (higher amplitude)<sup>54</sup>.

### The effect of a dynamic pressure-redistributing bed support surface upon systemic lymph flow and composition (*Gunther et al 2000*)

- Comparing the effect of dynamic (active) versus static (reactive) therapy on blood and lymph flow using an animal model: using prefemoral lymph and vascular catheters inserted under anaesthetic (USA).
- Upon recovery baseline lymph flow was measured (4-hour period) while moving, standing and feeding.
- Re-anaesthetised, 7 animals were placed on a foam mattress for 2 hours: the protocol was repeated for alternating pressure (designed specifically to achieve very low pressure on deflation) followed by a final 2-hour period on the foam mattress.
- The amount and composition of lymph produced indicated that alternating pressure produced a direct stimulatory effect on the lymphatic system<sup>55</sup>.



Figure 11: *AUTO logic 200* Mattress Replacement System

## Evidence from Laboratory Studies - continued

Although the following studies are a little older, they are included because they represent significant advances in the understanding of alternating pressure. The concept of off-loading the tissue, as much as possible for as long as possible, continues to underpin contemporary design.

### The effects of a unique alternating-pressure mattress on tissue perfusion and temperature (West et al 1995)

- A cross-over design compared a foam mattress and an Active APRM mattress using simultaneous measurements of subcutaneous tissue oxygen ( $O_2$ ) tension and temperature at the sacrum (USA).
- **5 volunteers** lay supine throughout the 2 hour study period: arterial blood gases were taken at baseline and end of each test period.
- Temperature (t) differences were seen between the two surfaces: t-foam rose by  $1.3^{\circ}C$  while t-AP was close to base-line and stable ( $p < 0.01$ ).
- Subcutaneous blood flow rose above baseline (mean 45%) in all subjects on Active APRM and in just two subjects (mean 19%) on the foam mattress.
- The authors conclude that AP systems provide a superior match between  $O_2$  supply and demand which may be particularly relevant for healing in patients with ulcers<sup>56</sup>.

*This invasive test from the laboratory of Dr Thomas Hunt, was one of the first to show the link between pressure and tissue perfusion (now replaced with non-invasive Doppler techniques). It clearly demonstrates that active alternating pressure stimulates perfusion while preventing an undesirable increase in skin temperature.*

### Static and dynamic anti-decubitus systems for ITU care patients (Schregel et al 1993)

- Comparing the effectiveness of one alternating (active) mattress with four static (reactive) mattress systems in **17 ITU patients** (Germany).
- IP, transcutaneous partial pressure of oxygen ( $tcPO_2$ ) and carbon dioxide ( $tcPCO_2$ ) in the sacral region were measured.
- The active (alternating) mattress, unlike the other mattresses, was shown to be capable of almost completely off-loading the tissue.
- The tissue off-loading resulted in a measurable reperfusion (by reactive hyperaemia) of the tissue<sup>57</sup>.

*This is a rare laboratory-style study in that rather than using healthy volunteers it was conducted in an intensive care unit. These data represent the performance of each of the mattresses in the most vulnerable individuals i.e. those for whom the support surfaces are ultimately intended.*

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*In addition to independent studies, ArjoHuntleigh operates a full-time test laboratory, producing research and development data for the whole product range; including mattresses, seat cushions and bed frames.*

## Reactive (Constant Lower Pressure)

### The Biomechanics Of Reactive Constant Lower Pressure

*TERMS: Reactive device, pressure redistribution, constant lower pressure, static system, powered passive system includes; low air loss, foam, air, gel and air fluidized systems.*

- Reactive (constant lower pressure or CLP (Figure 12)) systems typically reduce contact pressure at the skin-mattress interface by increasing the surface areas over which the individual is supported. Pressures will depend on the type of support surface and how it is adjusted: performance is described as a process of 'immersion' and 'envelopment'<sup>2</sup>. As the pressures do not change unless the individual makes a movement, these devices are now termed 'reactive'<sup>2</sup>.
- The degree of immersion can be described as a pressure redistributing continuum starting with foam which offers good base line products through to air foam combinations, low air loss and air fluidised systems.
- With greater pressure redistribution comes an increasing likelihood that vessel occlusion will be avoided. However, vessel patency is dependent on, amongst other things, the structure of the tissues and the haemodynamic status of the patient, so it is not valid to directly correlate constant interface pressure with a clinically 'safe' level for each individual.

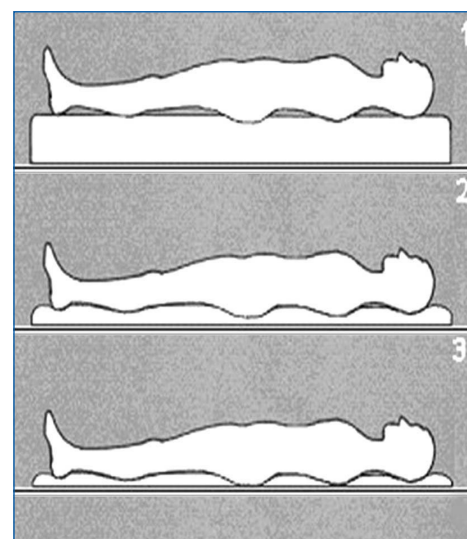


Figure 12: Reactive Pressure Redistribution

#### SYSTEMS MAY LOOK SIMILAR BUT...

***The degree of pressure redistribution is dependent on the degree of immersion and posture. In non-automatic systems care must be taken to correctly adjust the system for the individual patient.***

### Pressure Area Index (PAI)

The ability of a reactive support surface to off load pressure can be tested in the laboratory using full-length pressure mapping systems.

The results are presented in the terms of a PAI (Figure 13) i.e. the number of sensors reading below a certain threshold as a percentage of all load-bearing sensors. For mattress systems the thresholds are taken at 30, 20 and 10mmHg. For example, a PAI of 50% at 30mmHg means half of the body is experiencing pressure reduction below the 30mmHg threshold. The higher the PAI the better the pressure reduction provided.

This performance indicator, like the PRI used for alternating systems, describes the characteristics of the device; it cannot directly predict clinical outcome.

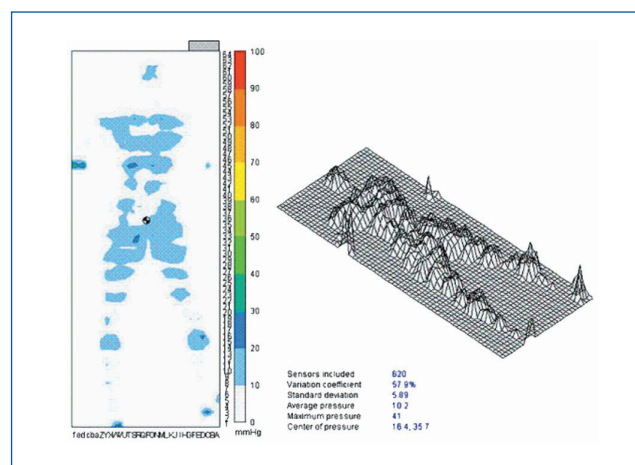


Figure 13: Pressure Area Index

## Evidence from Randomised Controlled Trials (RCTs)

*High quality and scientifically relevant RCT's are rare within CLP devices, in part due to the difficulty of obtaining statistically relevant sample sizes which tend to be large. Where studies are performed they tend to be in combination with other strategies e.g. bed frames*

### Profiling beds versus standard hospital beds: effects on pressure ulcer incidence outcomes (Keogh et al 2001)

- *Contoura* bed frame combined with a *Pentaflex*® MR (ArjoHuntleigh) evaluated against a Kings Fund hospital bed frame and a standard mattress.
- 70 patients randomised to the 2 systems.
- The combination of the *Contoura* bed and a *Pentaflex* MR was highly effective.
- An additional clinical survey of nursing staff highlighted significant assistance to nursing staff<sup>58</sup>.



Figure 14: Pentaflex Mattress Replacement

## Evidence from Prospective Outcome Studies

### Illustrative case study (Data on file 2005)

- A 10 year old patient with spinal muscular dystrophy, requiring overnight oxygenation, tube feeding and hourly turns, carried out by his mother.
- An Acer® system was provided to allow mechanical rotation of up to 40° every 30 minutes with 5 minute rest periods.
- The patient's quality of life has improved with a marked improvement seen in his chest condition, which has lead to fewer stays in hospital and a normal sleep pattern for both the patient and his family<sup>59</sup>.

### Bi-Flex® MR (Clinical Review 2003)

- 17 patients rested upon the *Bi-Flex* trolley (ArjoHuntleigh) mattress for 3.5 hours on average.
- Patient comfort was maintained and the need for repositioning reduced<sup>60</sup>.

### ConformX™ MR (Clinical Review 2003)

- A case series of 9 at risk patients evaluated the *ConformX* MR (ArjoHuntleigh).
- No pressure ulcers developed.
- All patients found the product very comfortable or comfortable<sup>61</sup>.



## Pentaflex® MR (Clinical Review 2003)

### Outcome Study 1

- 35 patients evaluated the *Pentaflex* MR in 24 different specialities.
- 60% were in very high risk category for pressure ulcer development.
- Demonstrated effective prevention of pressure ulcers<sup>62</sup>.

## An evaluation of the Breeze® System (Clinical Report 2001)

- 27 acute-care patients evaluated the *Breeze* system; 88% were at very high risk of pressure damage.
- 96% found the system comfortable and none developed pressure damage.
- The system is easy to use, comfortable and cost effective, making it an excellent alternative to alternating pressure and particularly useful for palliative care, burns and intractable pain<sup>63</sup>.

## Evaluation of a range of hospital replacement mattresses (Kernohan et al 1998)

- 12 different foams were tested as part of the decision process for tender.
- The *Pentaflex* mattress gave the optimum performance and was significantly less expensive than competitors<sup>64</sup>.

## The Pentaflex mattress: An interim technical report (Swain et al 1998)

### Outcome Study 2

- A longitudinal study documented the performance of the *Pentaflex* MR.
- 6 monthly re-test schedules showed it to sustain statistically superior pressure reduction throughout 36 months of continual usage<sup>65</sup>.

## The Role Of The Bed Frame

*In the past, the main interest surrounding pressure redistribution has been focussed on the mattress, as this is the part in closest contact to the patient. However, as interest in the relationship between pressure ulcers and shear force grows, more design effort has been made to reducing the impact of bed frame movement on the tissue. This is a highly relevant area of research as patients are most commonly nursed in a semi-upright (Fowler's) position and are increasingly encouraged to make independent adjustments to their position using remote controls: early studies are beginning to demonstrate very clear differences between bed frame design and subsequent loading on the tissue.*

## How does bed-frame design influence tissue interface pressure? A comparison of four different technologies designed for long-term or home care (Call et al 2007)

- The effect of 'sitting up' in bed (Fowler's position) on tissue IP was investigated using 4 different electric profiling beds (USA).
- IP was measured during the profiling sequence (supine-Fowler's-supine) at different anatomical locations including; the heel, buttocks, head and shoulder.
- The Minuet® 2 bed frame with Pro-contour® Advance profiling (ArjoHuntleigh), a specialised mattress platform, demonstrated significantly lower IP than the other 3 bed frames.
- The bed frame can augment the pressure redistribution offered by the foam mattress<sup>66</sup>.

## Evidence from Laboratory Studies

Much of the laboratory data aims to deliver a comparative test i.e. how different is the contact pressure between products in the same category (e.g. two foam mattresses) or other products in a different category (e.g. foam mattress compared to low air loss system). This type of simple data is strengthened where the effectiveness of a particular device has also been established by means of extensive field evaluation and/or blood flow studies.

Vulnerable individuals are rarely nursed flat and therefore PAI testing and subsequent results are taken in the commonly adopted positions, i.e. side lying and profiled at 45°.

### PAI effect of a 5 section bed frame and foam mattress (Data on file 2007)

The type of bed frame a mattress is placed on can also have an effect on pressure reduction.

- The body maps (Figure 15) presents a conventional profiling bed with a foam mattress showing a higher IP in the sacral area.
- The same mattress on a 5 section profiling bed frame, the *Pro-Contour Plus*, indicates much lower IP with good pressure reduction<sup>67</sup>.

### Breeze mattress PAI comparative data (Data on file 2004)

- An example of PAI on an optimally inflated low air loss MR system.
- The graph and body map showed the *Breeze* mattress produced a higher PAI, i.e. better pressure reduction below 30, 20 and 10 mmHg when compared to a standard foam mattress<sup>68</sup>.

### Pentaflex® mattress PAI comparative data (Data on file 2004)

An example of PAI on a pressure reducing (reactive) foam mattress.

- The results show that the *Pentaflex* mattress produced consistently better pressure reduction below 30mmHg in the supine, side lying and profiled at 45° positions<sup>69</sup>.

### ConformX® Mattress Replacement PAI comparative data (Data on file 2004)

An example of PAI on a visco elastic mattress.

- When compared to a well known competitor, the *ConformX MR* produced equivalent or better pressure redistribution<sup>70</sup>.

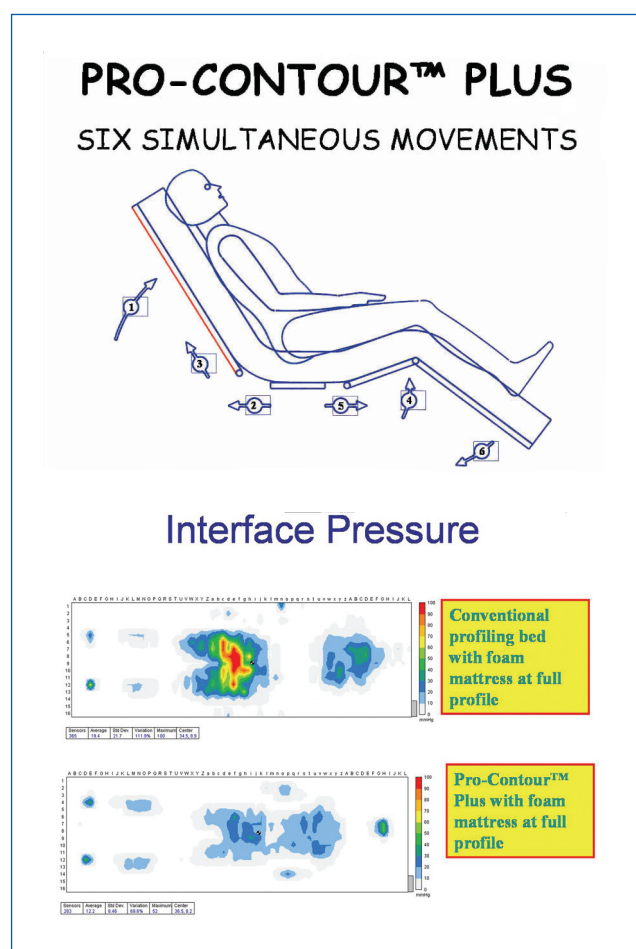


Figure 15: PAI Effect of a 5 section bed frame and a foam mattress

# The Economics

## Pressure Ulcer Management: The Economics

*A pressure ulcer represents a frequently encountered yet largely preventable, physical injury which can be associated with significant humanitarian and financial costs.*

### Costs associated with pressure ulcers

- Prevention and treatment initiatives.
- Nurse and patient education programmes.
- Equipment provision.
- Surgery.
- Medicines, dressings and nutritional supplements.
- Increased length of stay.
- Litigation.
- Back injury among nursing staff and carers.
- Containing and treating drug resistant infection in chronic wounds.

#### United States

- A prevalence survey of 86,932 patients in acute care facilities in 2009 identified overall pressure ulcer prevalence to be 11.9% of which 5% were facility acquired<sup>4</sup>.
- National cost in 2000 was \$2.2-\$3.6 billion annually<sup>8</sup>.

#### Europe

- A pilot survey identified 18.1% of patients with pressure ulcers across 5 European countries<sup>3</sup>.
- 1% of the healthcare budget in the Netherlands (€450 million annually) is spent on pressure ulcers<sup>71</sup>.
- 0.4–0.8% of the total healthcare budget in Hungary is spent on pressure ulcers<sup>6</sup>.
- The cost involved in the treatment of three category 4 pressure ulcers in one patient, over a 5 month period in Ireland was calculated as €119 thousand, with an estimated cost of €250 million per annum, to manage pressure ulcers across all care settings in Ireland<sup>72</sup>.

#### United Kingdom

- The number of patients with pressure ulcers has increased year on year since 2000<sup>75</sup>.
- 75,000 patients were admitted from the community to acute care solely for the treatment of pressure ulcers.
- 4% of NHS expenditure annually is spent on pressure ulcers<sup>6</sup>.
- The treatment of a category 4 pressure ulcer is estimated to cost £11 thousand<sup>6</sup>.
- In an average sized 500 bed hospital, pressure ulcer management costs are estimated to be in excess of £19 million per year<sup>7</sup>.

#### Australia

- A Victorian state wide survey of 6936 patients identified a point prevalence of 17.6%<sup>73</sup>.
- A study within the Australian public hospitals during 2001-2002 predicted that the economic loss due to lost bed days (purely due to pressure ulcers) was AU\$285 million<sup>74</sup>.

## The Economics

### Counting The Cost: The Value Of Outcome Measurement

*Cost minimisation is a balance between providing effective prevention and treatment strategies, while containing the associated costs.*

This is best achieved by ensuring that:

- Only effective therapeutic strategies are employed.
- Allocation of interventions is appropriate and timely.
- Outcomes are accurately measured, reviewed and acted upon.
- Multidisciplinary team involvement.
- Comprehensive and accurate documentation.
- Patient/client and carer education and involvement.
- Clinical audit.

These key steps are dependent upon a comprehensive set of skills including:

- Nurse education and assessment of patient/client vulnerability.
- Equipment selection.

Without this latter and vital element of measurement, it is impossible to clearly define the value of employing a pressure ulcer programme and therefore it is impossible to propose a cost-efficient strategy for continual improvement.

## Outcome Measures

*Given that the direct and indirect costs of pressure ulcer prevention and treatment strategies are high, it is appropriate to monitor a range of outcome measures, including:*

- Prevalence and incidence of pressure ulcers with case mix adjusted data.
- Severity of wounds.
- Protective and therapeutic strategies.
- Evidence of accurate, comprehensive and timely documentation.
- Level of nurse injury.
- Level of patient satisfaction.

Only when a comprehensive package of care is implemented *and monitored* over time is it possible to accurately report the value of the investment in prevention and treatment strategies – three case studies illustrate the point.

## Case Studies

### Case 1

The importance of periodic and focused pressure ulcer prevalence audit and benchmarking at one institute identified problem areas, which were then addressed through education and allocation of a range of pressure redistribution equipment (AlphaRelief® mattress (ArjoHuntleigh) through to DFS® 3 system (ArjoHuntleigh)). Subsequent prevalence audits provided clear evidence of a beneficial effect in lower pressure ulcer prevalence rates and a significant reduction in the number and severity of pressure ulcers<sup>76</sup>.



## Case studies - continued

### The Total Managed Equipment Approach

#### Case 2

Two acute care facilities totalling 1880 beds implemented a Total Managed Equipment (TME) package, which included pressure-relieving equipment, electric profiling bed frames, policy support, education, training and outcome tracking.

#### Key outcomes:

- Prevalence, incidence and severity of new ulcers has declined year on year (Figure 16).
- Costs have declined year on year<sup>77</sup>.

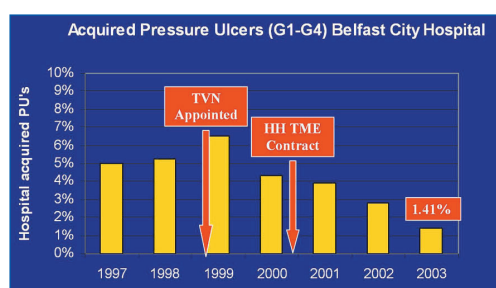
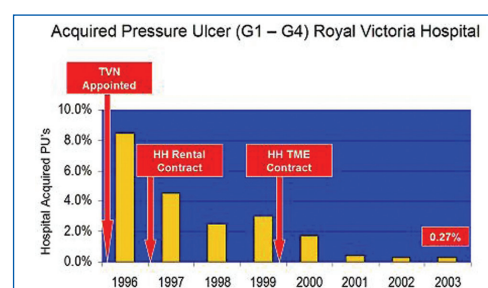


Figure 16: Data on file



#### Case 3

An 897 bed acute care facility implemented a TME package in 2001. Over subsequent years a number of quality outcomes were tracked and continual improvements recorded.

#### Key outcomes:

- Prevalence, incidence and severity of new ulcers has declined year on year (Figure 17).
- Equipment allocation improved by means of education and policy revision.
- Documentation improved.
- Number of reported back injuries to nurses has halved<sup>78</sup>.

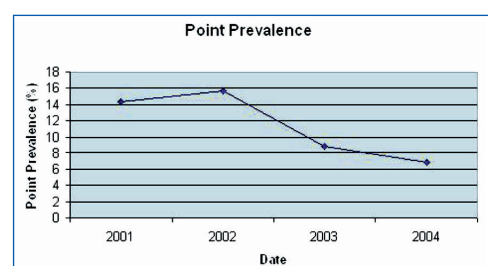


Figure 17: Data on file

## Evidence Based Recommendations

Whilst robust evidence is scarce there are some general recommendations to guide practice;

- All patients, including those at an elevated risk of pressure ulcers, should be provided with a *good quality* pressure redistributing foam mattress for base line prevention<sup>1</sup>.
- Patients at an elevated risk of pressure, should be provided with an active (alternating) pressure mattress<sup>1</sup>.
- Patients with pressure ulceration should be placed on a support surface that is properly matched to the individual's needs for pressure redistribution, shear reduction, and microclimate control<sup>1</sup>.
- Recommendations for low air loss or air fluidised systems specifically for healing, are generally based upon outdated research and obsolete products, so should be treated with caution.
- Equipment selection should be based on holistic assessment and regular patient reassessment, rather than any one single factor<sup>1</sup>.

## Selecting the Correct Equipment

Optimising clinical outcomes depends upon the skilled assessment of vulnerable individuals, followed by a comprehensive and multidisciplinary plan of care: it is unlikely that equipment will provide the desired outcomes when used in isolation.

### Considerations:

- The desired outcome e.g. prevention, rapid healing, palliative care, comfort etc.
  - What do I actually want to achieve for my patient/client – what are his/her goals?
- The environment in which the patient/client is nursed, in particular, is carer access limited?
  - Where will the person be cared for – what are the implications?
- The intrinsic and extrinsic factors associated with the patient/client and his/her co-morbidities; including independent mobility, continence and nutrition.
  - What other problems will we have to deal with and how can the device help?
- The equipment and funds available.
  - How much can I spend in caring for this person?
- The ability for, and frequency of patient reassessment and repositioning.
  - How much additional nursing care can I or the patient/clients carers realistically offer?

**Note:** Caution should be applied when using an assessment scale as a direct indicator of which product should be provided. Such tools generally have a low inter-rater reliability and a low predictive validity and tend towards over-prescription. Patient assessment should be holistic, and provided the factors listed above are considered and addressed, the outcomes will remain positive.

As a guide, the allocation of products should be considered as a continuum where the least sophisticated, manually adjusted or passive systems require the greatest degree of skilled assessment and intervention. The fully automated, dynamic or active systems may provide optimum therapy with minimal supervision<sup>76</sup>.

## Cost Effective Solutions

Well designed cost-effectiveness studies are extremely rare in the field of pressure ulcer management, while the range of equipment and nursing interventions is broad; this leaves healthcare providers with the problem of choosing a cost efficient strategy for their clients.

In increasingly stretched health services, it is tempting to select the lowest cost option, but this does not always result in the lowest overall cost to the facility.

For example, one study shows very little difference in outcome (prevention) between a foam (reactive) mattress and a dynamic (active) overlay, yet once the additional care required for the foam group is considered, the dynamic system proves more cost effective<sup>18</sup>.

Similarly, the largest (n=1971) well designed RCT undertaken to date, comparing active alternating MR's with active alternating overlays, found that patients incurred pressure damage 10 days sooner on the overlay system and cost more to treat overall. The study concluded that lower costs and greater health benefits were attributed to the alternating MR systems<sup>16</sup>.

Most recently, an illustrative case study using a computer generated model highlighted that pressure relieving surfaces can lead to financial savings for a hospital when used appropriately<sup>7</sup>.

## Summary & Abbreviations

### Summary

The material presented within this document has enabled us to present an evidence-based guide from which you can begin the process of equipment selection. By providing excellent products and services to complement your skilled holistic assessment we are confident that ArjoHuntleigh will prove to be your ideal partner in achieving the goal of cost-effective care.

If you would like more information, may we invite you to browse our website [www.ArjoHuntleigh.com](http://www.ArjoHuntleigh.com) where you will find comprehensive abstracts for many of the papers included in this brochure and information on our products and services.

Abbreviation	Full term
ACE	Advanced Clinical Education
AP	Alternating Pressure
APRM	Alternating Pressure Redistributing Mattress
ARDS	Acute Respiratory Distress Syndrome
CLP	Constant Lower Pressure
CPR	Cardio Pulmonary Resuscitation
DFS 3	Dynamic Flotation System 3
DVT	Deep Vein Thrombosis
ICU	Intensive Care Unit
IP	Interface Pressure
ITU	Intensive Therapy/Care Unit
MR	Mattress Replacement
NHS	National Health Service
PAI	Pressure Area Index
PRI	Pressure Relief Index
O <sup>2</sup>	Oxygen
RCT	Randomised Controlled Trial
RH	Relative Humidity
SCI	Spinal Cord Injury
t	Temperature
TME	Total Managed Equipment

## Study Design

Study design	Author	Short title	Year	Page
RCT	Malbrain ML	<i>Nimbus</i> 3 mattress in ICU	2010	5
RCT	Finnegan M	<i>Nimbus</i> 3 Professional mattress in reconstructive surgery	2007	5
RCT	Iglesias C	Alternating pressure vs. alternating overlay	2006	6
RCT	Perkins GD	<i>Nimbus</i> 3 mattress CPR efficiency	2003	6
RCT	Folens B	<i>AlphaXcell</i> mattress vs. foam mattress	2001	6
RCT	Keogh A	<i>Contoura</i> bed with <i>Pentaflex</i> mattress vs. Standard bed	2001	16
RCT	Russell L	<i>Nimbus</i> 3 mattress & <i>Cairwave</i> Therapy	2000	6
RCT	Evans D	<i>Nimbus</i> 3 mattress vs. overlay	2000	6
RCT	Land L	<i>Nimbus</i> 3 mattress vs. overlay	2000	6
RCT	Taylor L	<i>Trinova</i> 3 mattress in acute care	1999	6
Clinical Outcome Study	Ward C	<i>Alpha Response</i> in acute care	2010	7
Clinical Outcome Study	Wijnands P	<i>AUTO logic</i> 200 System in pressure ulcer treatment	2006	7
Clinical Outcome Study	Clark M	<i>NIMBUS logic</i> 200 and <i>AUTO logic</i> Systems in pressure ulcer treatment	2005	7
Clinical Outcome Study	Henn G	<i>AUTO logic</i> System in pressure ulcer prevention	2004	9
Clinical Outcome Study	Still JM	<i>Cairwave</i> Therapy System in burns treatment	2003	8
Clinical Outcome Study	Marin EM	<i>Trinova</i> MR system Critical Care	2002	8
Clinical Outcome Study	Wallenstein S	<i>Cairwave</i> Therapy System ulcer treatment	2002	8
Clinical Outcome Study	Clark M	Cost model: alternating pressure	2001	8
Clinical Outcome Study	Jones I	<i>Nimbus</i> paediatric system in critically ill infants	2001	11
Clinical Outcome Study	Phillips L	<i>Cairwave</i> Therapy System in Critical care and bariatric care	2001	10
Clinical Outcome Study	Phillips L	<i>Cairwave</i> Therapy System Critical Care	2000	8
Clinical Outcome Study	Dunn R	<i>Nimbus</i> & <i>Autoexcel</i> systems in spinal care	2008	10
Clinical Outcome Study	Fox C	<i>Nimbus</i> 3 mattress in vascular surgery	2000	11
Clinical Outcome Study	Calver M	<i>Cairwave</i> Therapy System in pressure ulcer treatment	1999	8
Clinical Outcome Study	Swain I	<i>Pentaflex</i> MR performance study	1998	17
Laboratory Study	Stockton	<i>Aura logic</i> seat cushion	2008	12
Laboratory Study	Goossens R	<i>AUTO logic</i> 200 System vs. Duocare Plus mattress (Talley Medical) & Proficare mattress (KCI)	2008	12
Laboratory Study	Rithalia SVS	<i>Nimbus</i> 3 mattress & <i>NIMBUS logic</i> 200 system vs. Duo 2 mattress (Hill Rom Inc)	2007	13
Laboratory Study	Call E	<i>Minuet</i> 2 bed frame & Pro-Contour Advance bed vs 3 other bed frames	2007	17



Study design	Author	Short title	Year	Page
Laboratory Study	ArjoHuntleigh	Pro-Contour Plus 5 section profiling and mattress	2007	18
Laboratory Study	Heath G	<i>AUTO logic</i> 200 system vs. Breeze mattress	2006	13
Laboratory Study	van Schie C	<i>Nimbus</i> 3 mattress vs. Duo mattress (Hill Rom Inc)	2004	13
Laboratory study	ArjoHuntleigh	<i>Breeze</i> mattress PAI comparative data	2004	18
Laboratory study	ArjoHuntleigh	<i>Pentaflex</i> mattress PAI comparative	2004	18
Laboratory study	ArjoHuntleigh	<i>ConformX</i> mattress MR PAI comparative data	2004	18
Laboratory study	Gunther RA	Active vs reactive therapy on blood and lymph flow	2000	13
Laboratory study	West J	AP vs foam mattress using blood gases and temperature	1995	14
Laboratory study	Schregel W	Active mattress vs. 4 reactive mattresses	1993	14
Audit data/Evaluations	ArjoHuntleigh	<i>Nimbus</i> mattress, <i>Autoexcel</i> mattress, <i>AlphaXcell</i> mattress in low weight patients	2004	7
Audit data/Evaluations	Manriques N	<i>Nimbus</i> 3 mattress and <i>Contoura</i> 1080 bed frame in obeses patients	2004	9
Audit data/Evaluations	Mathews J	<i>Nimbus</i> 3 mattress in burns patient	2003	9
Audit data/Evaluations	ArjoHuntleigh	<i>Bi-Flex</i> MR	2003	16
Audit data/Evaluations	ArjoHuntleigh	<i>ConformX</i> MR in pressure ulcer care	2003	16
Audit data/Evaluations	ArjoHuntleigh	<i>Pentaflex</i> MR in pressure ulcer care	2003	17
Audit data/Evaluations	ArjoHuntleigh	<i>Breeze</i> mattress in pressure ulcer care and comfort	2001	17
Audit data/Evaluations	Kernohan W	<i>Pentaflex</i> mattress vs. 11 foams	1998	17
Case study	Ashton J	<i>Nimbus</i> 3 Professional system in SCI patients and ulcer treatment	2006	10
Case study	Ward C	<i>Nimbus</i> Professional: Using complete pressure off-loading to treat a sacral pressure ulcer	2010	11
Case study	Phillips L	<i>Nimbus</i> 3, <i>Nimbus</i> 4 and <i>Nimbus</i> Professional mattress replacements: Combining active (alternating) therapy with <i>Wound Valve</i> Technology.	2010	11
Case study	ArjoHuntleigh	<i>Acer</i> mattress in spinal muscular dystrophy (child)	2005	16
Case study	Thompson G	Transfer chair TC300 for larger patient	2004	9
Case study	Schaffer J	<i>Nimbus</i> 3 mattress in post operative flap repair	2002	10
Case study	Doubleman J	<i>Nimbus</i> 3 mattress in post operative flap repair	2001	10
Case study	Vrijdag H	<i>Nimbus</i> 3 mattress in burns treatment	2001	9
Case study	Doubleman J	<i>Nimbus</i> 3 mattress in SCI patient	2000	10

## References

1. EPUAP & NPAUP (2009). Prevention of pressure ulcers: Quick Reference Guide. Washington DC: National Pressure Ulcer Advisory Panel EPUAP & NPAUP (2009). Treatment of pressure ulcers: Quick Reference Guide. Washington DC: National Pressure Ulcer Advisory Panel
2. National Pressure Ulcer Advisory Panel (NPUAP). Pressure Ulcer Definition and Stages. 2007; [www.npuap.org/documents/PU\\_definition\\_stages.pdf](http://www.npuap.org/documents/PU_definition_stages.pdf)
3. Vanderwee K, Clark M, Dealey C et al (2007). Pressure ulcer prevalence in Europe: a pilot study. *Journal of Evaluation in Clinical Practice*; 13: 227-235
4. VanGilder C, Amlung S, Harrison P et al (2009). Results of the 2008-2009 international pressure ulcer prevalence survey and a 3 year, acute care, unit specific analysis. *Ostomy Wound Management*; 55(11): 39-45
5. Olshansky K (2008). The 10 most important questions concerning pressure ulcers and quality of care. *Advances in Skin and Wound Care*; 21(11): 505-8
6. Bennet G, Dealey C, Posnett J (2004). The cost of pressure ulcers in the UK. *Age and Ageing*; 33(30): 230-235
7. Trueman P, Whitehead SJ (2010). The economics of pressure relieving surfaces: an illustrative case study of the impact of high specification surfaces on hospital finances. *International Wound Journal*; 7: 48-54
8. Whittington KT, Briones R (2004). National prevalence and incidence study: 6 year sequential acute care data. *Advances in Skin and Wound Care*; 17: 490-494
9. Protecting 5 million lives from harm campaign. <http://www.ihl.org/IHL/programs/campaign> (Accessed 01/10/07)
10. Landis EM (1930). Micro-injection studies of capillary blood pressure in human skin. *Heart*; 15:209-228
11. Williams SA et al (1988). Dynamic measurement of human capillary blood pressure. *Clinical Science*; 74: 507-512
12. Exton-Smith AN, Sherwin RW (1961). The prevention of pressure sores significance of spontaneous bodily movements. *The Lancet*; 2(7212): 1124-1126
13. Keane FX (1978). The minimum physiological movement requirement for man supported on a soft surface. *Paraplegia*; 16:383-389
14. Malbrain M, Hendriks B, Wijnands P et al (2010). A pilot randomised controlled trial comparing reactive air and active alternating pressure mattresses in the prevention and treatment of pressure ulcers among medical ICU patients. *Journal of Tissue Viability*; 19(1):7-15
15. Finnegan MJ (2008). Comparing the effectiveness of a specialised alternating air pressure mattress replacement system and an air-fluidised integrated bed in the management of post-operative flap patients: A randomised controlled study. *Journal of Tissue Viability*; 17(1); February 2008
16. Iglesias C, Nixon J, Cranny G et al (2006). Pressure relieving support surfaces (PRESSURE) trial: cost effectiveness analysis. *British Medical Journal*; 332 (7555): 1413-1415
17. Perkins GD, Benny R, Giles S et al (2003). Do different mattresses affect the quality of cardiopulmonary resuscitation? *Intensive Care Medicine*; 29(12): 2330-2335
18. Folens B (2001). Comparing the cost: A study of the AlphaXcell® alternating pressure overlay system compared with the Tempur® foam mattress overlay in combination with patient repositioning. Masters Thesis, University of Ghent, Belgium
19. Russell L, Reynolds TM (2000). Randomised controlled trial of two pressure-relieving systems. *Journal of Wound Care*; 9(2): 52-55
20. Evans D, Land L, Geary A (2000). A clinical evaluation of the Nimbus 3 alternating pressure mattress replacement system. *Journal of Wound Care*; 9(4): 181-186
21. Land L, Evans D, Geary A et al (2000). A clinical evaluation of an alternating pressure mattress replacement system in hospital and residential care settings. *Journal of Tissue Viability*; 10(1): 6-11
22. Taylor L (1999). Evaluating the Pegasus Trinova: a data hierarchy approach. *British Journal of Nursing*; 8(12): 771-778
23. Ward C (2010). The value of systematic evaluation in determining the effectiveness and practical utility of a pressure-redistributing support surface. *Journal of Tissue Viability*; 19(1): 22-27
24. Wijnands P, Malbrain M, Jans A et al (2006). A descriptive quantitative study to determine the effectiveness of the AUTO logic 200 dynamic mattress in the prevention and healing of a pressure ulcer. Poster presentation, EWMA 2006
25. Clark M, Hiskett G, Russell L (2005). Evidence-based practice and support surfaces: are we throwing the baby out with the bath water? *Journal of Wound Care*; 14(10): 455-458
26. Low weight patients. ArjoHuntleigh Clinical Report 2004
27. Still JM, Wilson J, Rinker C et al (2003). A retrospective study to determine the incidence of pressure ulcers in burns patients using an alternating pressure mattress. *Burns*; 29: 505-507
28. Marin EM (2002). Prospective clinical outcome study of the effectiveness of a dynamic mattress replacement system in the critically ill patient. Presented at European Wound Management Association
29. Wallenstein S, Carasa M, Kapil-Pair N et al (2002). Defining the rates of healing of pressure ulcers. Poster presentation, European Pressure Ulcer Advisory Panel, September
30. Clark M (2001) Models of pressure ulcer care: costs and outcomes. *British Journal of Health Care Management*; 7(10): 412-416
31. Phillips L (2000). Cost effective strategy for managing pressure ulcers in critical care: a prospective, non-randomised, cohort study. *Journal of Tissue Viability*, Special supplement; July
32. Calver M (1999). Pressure ulcer management in critical care, Cairwave Therapy System™ - A clinical outcome study. Poster presentation, European Wound Management Conference
33. Matthews J (2003). Evaluation of an alternating pressure support surface for burn treatment. ArjoHuntleigh Clinical Report
34. Vrijdag H, Blot S (2001). Use of the Nimbus 3 in a patient with severe burns: A case study. Poster presentation at Vlaamse Vereniging Intensive Zorgen Verpleegkundigen (WIZV). 12th October, Ghent, Belgium
35. Manriques N (2004). Speciality support surface selection for hospitalised obese patients. Poster presentation, Journal of Wound Care Conference; May/June
36. Henn G, Taylor H, Russell L (2004). A two centred prospective study to determine the utility of a dynamic mattress replacement and overlay system. Presented at the WUWHS Conference, Paris
37. Thompson G (2004). Achieving handling excellence for the larger patient with a specialist 'transfer chair. Poster presentation, Wounds UK, Harrogate, UK

## References

38. Phillips L (2001). Pressure relief and the critically ill bariatric patient. Poster presentation, Innovations in Wound Care Conference, September
39. Schaffer J (2002). Successful healing and cost effective care post-operative flap repair of a pressure ulcer. ArjoHuntleigh Clinical Report
40. Doubleman J (2001) Alternating support surface effectiveness with a muscle flap closure of a pressure sore. ArjoHuntleigh Clinical Report
41. Dunn RN, Stander J (2008). Pressure sores in spinal cord injury: Active intervention saves costs. *Southern African Journal of Critical Care*; 24(1): 8-12
42. Ashton J, Sturges J (2006). Back to basics – simple measures resolve a complex wound: Pressure off-loading and honey. Presented at EPUAP
43. Doubleman J (2000). Management of pressure with an alternating pressure relieving support surface. ArjoHuntleigh Clinical Report
44. Fox C, Burgess Allen N (2000). An evaluation of alternating pressure for patients undergoing vascular surgery: A new mattress replacement system with a low pressure heel section. Poster presentation at the 7th European Conference on Advances in Wound Management, November, Harrogate, UK
45. Tweed C (2009) Caring for a severely disabled child - what a difference a good nights sleep makes! ArjoHuntleigh Clinical Report
46. Jones I, Tweed C, Marron M (2001). Pressure area care in infants and children: Nimbus Paediatric System. *British Journal of Nursing*; 10(12): 789-795
47. Phillips L (2010) The Nimbus 3, Nimbus 4 and Nimbus Professional pressure redistributing mattress replacements: Combining Active (alternating) therapy with Wound Valve Technology for the prevention of pressure ulcers and the management of complex wounds in high risk patients. *Wounds UK*; 6(2):116-122
48. Ward C, Wubbels M (2010). Using complete pressure off-loading and advanced wound care to treat a complex sacral pressure ulcer. Poster presentation EWMA 2009
49. Clark M (2001). Pressure ulcer prevention. In: M.Morison (ed) The prevention and treatment of pressure ulcers, Edinburgh: Mosby
50. Stockton L, Rithalia S (2008). Is dynamic seating a modality worth considering in the prevention of pressure ulcers? *Journal of Tissue Viability*; 17(1): 15-21
51. Goossens R, Rithalia SVS (2008). Physiological response of the heel tissue on pressure relief between three alternating pressure air mattresses. *Journal of Tissue Viability*; 17(1): February 2008
52. Rithalia SVS, Heath GH (2007). Alternating pressure redistribution mattresses: appearances can be deceptive. In Press
53. Heath GH, Rithalia SVS (2006). Effect of support surface design on skin temperature. European Pressure Ulcer Advisory Panel
54. Van Schie C, Ragunathan S, Rithalia S et al (2004). Heel blood flow studies using alternating pressure air mattress systems in diabetic patients. Manchester Diabetes Centre, Manchester Royal Infirmary. Diabetes Foot Clinic, Disablement Services Centre, Withington Hospital. School of Health Care Professions, University of Salford
55. Gunther RA, Clark M (2000). The effect of a dynamic pressure-redistributing bed support surface upon systemic lymph flow and composition. *Journal of Tissue Viability*; 10(3 suppl): 10-15
56. West J, Hopf H, Szaflarski N et al (1995). The effects of a unique alternating pressure mattress on tissue perfusion and temperature. European Tissue Repair Society Conference
57. Schregel W, Hube M, Finterswalder H (1983). Static and dynamic anti-decubitus systems for ITU care patients. *Journal of Tissue Viability*; 3(4); 9-14
58. Keogh A, Dealey C (2000). Profiling beds versus standard hospital beds: effects on pressure ulcer incidence outcomes. *Journal of Wound Care*; 10(2): 15-19
59. ArjoHuntleigh data on file 2005
60. Bi-Flex MR. ArjoHuntleigh Clinical Review 2003
61. ConformX MR. ArjoHuntleigh Clinical Review 2003
62. Pentaflex MR. ArjoHuntleigh Clinical Review 2003
63. An evaluation of the Breeze System. ArjoHuntleigh Clinical Report 2001
64. Kernohan W, Whiterow A, Allen-Hamilton s et al (1999). Evaluation of a range of hospital replacement mattresses. *Journal of Wound Care*; 8(10), 495-497
65. Swain I, Norman D, Morant S (1998). The Pentaflex mattress: An interim report. ArjoHuntleigh Technical Report
66. Call E, Baker L (2008). How does bed frame design influence tissue interface pressure? A comparison of four different technologies designed for long term or home care. *Journal of Tissue Viability*; 17(1); February
67. ArjoHuntleigh data on file 2007
68. ArjoHuntleigh data on file 2004
69. ArjoHuntleigh data on file 2004
70. ArjoHuntleigh data on file 2004
71. Severens JL, Habraken JM, Duivenvoorden S et al (2002). The cost of illness in pressure ulcers in the Netherlands. *Advances in Wound Care*; 15: 72-77
72. Gethin G, Jordan-O'Brien J, Moore Z (2005). Estimating costs of pressure area management based on a survey of ulcer care in one Irish hospital. *Journal of Wound Care*; 14(4): 162-165
73. Victorian Quality Council,VQC State-wide PUPPS Report—2006: Pressure ulcer point prevalence survey. Department of Human Services 2006. [www.health.vic.gov.au/qualitycouncil](http://www.health.vic.gov.au/qualitycouncil)
74. Graves N, Birrell FA, Whitby M (2005). Modelling the economic losses from pressure ulcers among hospitalized patients in Australia. *Wound Repair and Regeneration*; 13: 462-467
75. Clark M (2004). Pressure ulcers: Have we overlooked valuable data? *International Wound Journal*; 1(2): 143
76. Phillips L (2004). Optimise outcomes and reduce clinical risk by setting up pressure relieving equipment correctly. *Nurse 2 Nurse*; 4(3): 1-5
77. Rogan J, Stirling N, Cochrane J et al (2004) Pressure ulcer prevention: The never ending journey. NT Awards, Nursing Times; 100 (46): 71
78. Purvis K, Pearman A (2005). How the use of electric profiling beds can reduce the prevalence of pressure ulcers. *Professional Nurse*; 20 (8): 46-48

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